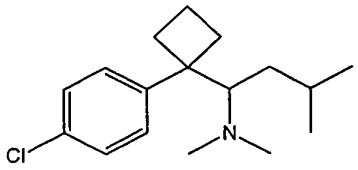
WHAT IS CLAIMED IS:

1. A pharmaceutical composition for treating or preventing obesity, comprising the crystalline sibutramine methanesulfonate hemihydrate of formula (I).



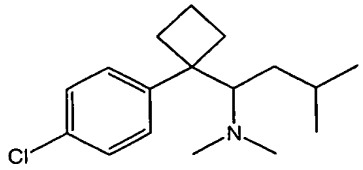
• $CH_3SO_3H \cdot 1/2H_2O$ (I)

2. The pharmaceutical composition of claim 1, wherein the 2θ values of the major peaks in the X-ray diffraction spectrum of the crystalline sibutramine methanesulfonate hemihydrate are:
8.2±0.2, 10.8±0.2, 11.7±0.2, 12.0±0.2, 12.3±0.2, 15.8±0.2, 16.4±0.2, 17.4±0.2, 17.4±0.2, 17.8±0.2, 19.0±0.2, 21.2±0.2, 21.9±0.2, 22.2±0.2, 22.8±0.2, 23.3±0.2, 24.4±0.2, 24.9±0.2, 25.3±0.2, 25.6±0.2 and 26.8±0.2.

3. The pharmaceutical composition of claim 1 or 2, further comprising a pharmaceutically acceptable carrier, diluent or excipient.

4. The pharmaceutical composition of claim 1, wherein the crystalline sibutramine methanesulfonate hemihydrate of formula (I) is present in an amount ranging form 1 to 50mg.

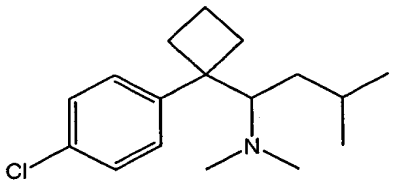
5. The crystalline sibutramine methanesulfonate hemihydrate of formula (I).



• $CH_3SO_3H \cdot 1/2H_2O$ (I)

6. The crystalline sibutramine methanesulfonate hemihydrate of formula (I) of claim 5, of which the 2θ values of the major peaks in the X-ray diffraction spectrum are:
8.2±0.2, 10.8±0.2, 11.7±0.2, 12.0±0.2, 12.3±0.2, 15.8±0.2, 16.4±0.2, 17.4±0.2, 17.4±0.2, 17.8±0.2, 19.0±0.2, 21.2±0.2, 21.9±0.2, 22.2±0.2, 22.8±0.2, 23.3±0.2, 24.4±0.2, 24.9±0.2, 25.3±0.2, 25.6±0.2 and 26.8±0.2.

7. A method of preparing the crystalline sibutramine methanesulfonate hemihydrate according to claim 5 or 6, which comprises reacting sibutramine of formula (II) with methanesulfonic acid dissolved in a mixture of an organic solvent and water.



(II)

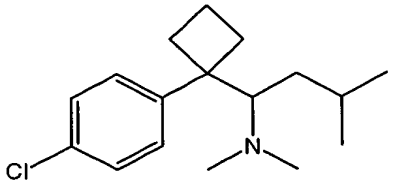
8. The method of claim 7, wherein methanesulfonic acid is employed in an amount ranging from 1 to 2 mole equivalents, based on 1 mole of sibutramine of formula (II).

9. The method of claim 7, wherein water is employed in an amount ranging from 0.5 to 5 mole equivalents, based on 1 mole of sibutramine of formula (II).

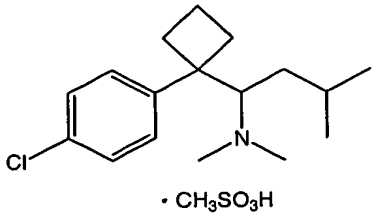
10. The method of claim 7, wherein the organic solvent is an ester selected from the group consisting of ethyl acetate, n-propyl acetate, isopropyl acetate and n-butyl acetate; an ether selected from the group consisting of diethyl ether, diisopropyl ether and t-butyl methyl ether; a ketone selected from the group consisting of acetone, methyl ethyl ketone; or a mixture thereof.

11. A method of preparing the crystalline sibutramine methanesulfonate

hemihydrate according to claim 5 or 6, which comprises (i) reacting sibutramine of formula (II) with methanesulfonic acid in an anhydrous organic solvent to obtain anhydrous sibutramine methanesulfonate of formula (III); and (ii) bringing the sibutramine methanesulfonate of formula (III) into contact with water in an organic solvent.



(II)



(III)

12. The method of claim 11, wherein methanesulfonic acid is employed in an amount ranging from 1 to 2 mole equivalents, based on 1 mole of sibutramine of formula (II).

13. The method of claim 11, wherein water is employed in an amount ranging from 0.5 to 5 mole equivalents, based on 1 mole of anhydrous sibutramine methanesulfonate of formula (III).

14. The method of claim 11, wherein the anhydrous organic solvent of step (i) is an ester selected from the group consisting of ethyl acetate, n-propyl acetate, isopropyl acetate and n-butyl acetate; a ketone solvent selected from the group consisting of acetone, methyl ethyl ketone and methyl isobutyl ketone; an ether selected from the group consisting of ethyl ether, isopropyl ether and t-butyl methyl ether; toluene; or a mixture thereof.

15. The method of claim 11, wherein the organic solvent of step (ii) is an ester

selected from the group consisting of ethyl acetate, n-propyl acetate, isopropyl acetate and n-butyl acetate; an ether selected from the group consisting of diethyl ether, diisopropyl ether and t-butyl methyl ether; a ketone selected from the group consisting of acetone, methyl ethyl ketone and methyl isobutyl ketone; or a mixture thereof.